MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

Statement for the record of

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to the

PRACTICING PHYSICIANS ADVISORY COUNCIL

RE: Medicare Competitive Acquisition Program for Physician-Administered Drugs

August 22, 2005

The Medical Group Management Association (MGMA) appreciates the opportunity to submit this statement to the Practicing Physicians Advisory Council (PPAC) regarding the interim final rule published July 6, 2005, that would implement the Medicare Competitive Acquisition Program (CAP) for physician-administered drugs. MGMA has consistently expressed its concern that Medicare reimburse providers appropriately for both the cost of drugs administered in the outpatient setting and the cost of physician administration services. The Medicare Prescription Drug, Improvement and Modernization Act (MMA) dramatically altered reimbursement in both of these areas, and MGMA remains extremely concerned about the adequacy of reimbursement levels.

We understand that on August 3, the Centers for Medicare & Medicaid Services (CMS) suspended the CAP vendor bidding process, thus delaying implementation of the interim final rule. The notice clarifies that the Agency continues to seek comment on the rule, but that providers will be unable to acquire drugs through the program until July 2006. We applaud CMS for recognizing that the program will not be ready for implementation by January 1. MGMA looks forward to working with the PPAC and CMS as the vendor and medical communities evaluate how the CAP can be implemented in a responsible manner.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead some 11,500 health care organizations in which more than 240,000 physicians practice. MGMA leads the industry with its research into practice costs. In fact, MGMA has conducted

extensive surveys of medical practice costs for more than 50 years, and our data are widely respected as accurate benchmarks of the expenses associated with caring for patients.

Research findings that MGMA, the American Medical Association and a number of medical specialty associations conducted earlier this year regarding the drug reimbursement issue, found that the ability for physician practices to obtain drug discounts varied widely by specialty, geography and other factors. MGMA remains gravely concerned about the adequacy of Medicare payments and the lack of timely notification of payment changes to providers rendering these drugs.

The competitive acquisition program (CAP) may offer a viable alternative for providers who are unable to obtain drugs at or below the average sales price plus six percent (ASP+6) rates. However, the program must be administered in such a way that it does not further complicate administrative aspects of physician administration of drugs, requires timely delivery of drugs and continues to be appealing to drug vendors. MGMA applauds many aspects of the interim final rule, including the national scope of the vendor distribution region, phase-in drug coverage and exclusion, and various other provisions. However, we remain concerned regarding several important implementation aspects of the CAP. To assist the PPAC in advising CMS to make this program a viable option for medical group practices, MGMA offers the following comments and recommendations.

Inclusion of CAP in the calculation of ASP

MGMA asserts that the inclusion of CAP vendor prices in the calculation of the ASP is inappropriate and thus rejects CMS' position: "We do not believe that we have the statutory authority to exclude prices determined under the CAP from the computation of ASP under section 1847A of the Act. Section 1847A(c)(2) of the Act contains a specific list of sales that are exempt from the ASP calculation, and sales to vendors operating under CAP are not included on that list. Prices offered under the CAP must therefore be included in ASP calculations." 70 Fed. Reg. 39077. MGMA simply views the inclusion of the CAP rates in the calculation of ASP as duplicative and highly unfair to physicians electing to not participate in the CAP. *MGMA recommends to PPAC that they work with CMS and Chairman Bill Thomas of the House Ways and Means Committee to clarify how Congress intended the ASP and CAP systems to co-mingle, if at all.*

Group practice billing

The interim final rule would mandate that if one physician in a group practice enrolls in the CAP program, all physicians in the group must adhere to the participation decision of the individual. This

highly discriminatory policy places solo practitioners in a much better position than group practices when it comes to evaluating CAP enrollment. MGMA believes that the participation decision should be determined on an individual physician level and should not be attributed to a whole group.

Also of significance, this is the only Medicare enrollment decision where the decision of an individual provider binds the entire group practice. Medicare participation is made on an individual basis and may be billed under a group number. *Thus, MGMA strongly recommends that PPAC reject this portion of the CAP interim final rule and urge CMS to withdraw the group practice provision found in 42 CFR 414.908(a)(4).*

Prescription information from physician

The data elements for the CAP order (42 CFR 414.908(a)(3)(v)) are duplicative to those submitted on a service claim and do not reflect either a drug prescription or drug order. Generally, prescriptions require: (1) date of prescription; (2) patient name; (3) physician identifying information including name, group name, practice address and telephone number; (3) drug, dosage, quantity and refill(s) permitted; (4) patient instructions; (4) DEA/LIC number (if applicable); and (5) signature. Drug orders conducted under the ASP+6 system generally require: (1) physician/group identifying information including name, practice address and telephone number; (2) billing and shipping address; (3) drug, shipment size (vial) and quantity; and (4) DEA/LIC number (if applicable).

As currently written, MGMA strongly believes that the requirements are too burdensome and do not reflect current industry standards. Instead, the data elements reflect requirements for the Medicare billing system and amount to mandating that CAP providers submit two claims for their services – one for the prescription order and the other for the drug administration. The burden of the collection of claims data should be placed on Medicare and not CAP participating physicians. *MGMA recommends that many of the data elements sought in the rule be obtained through claims adjudication and not CAP orders. Examples of these elements include: patient contact information (address and telephone), date of birth, allergies, height, weight, ICD-9 codes, supplemental health insurance information and Medicaid information.*

CMS asserts in the interim final rule that they are unable to disclose this information to the CAP vendors due to patient privacy law/regulation, and offers as an example the restrictions on disclosure mandated by the Health Insurance Portability and Accountability Act. MGMA flatly rejects this contention, as it does not accurately portray the CAP vendor-CMS contractor-CAP physician relationship. This relationship is

based on claims payment, which is a covered relationship under the HIPAA privacy law for permissible disclosure. Within the exception, information must be the "minimum necessary," which arguably describes the information sought above. Therefore, as a transaction for treatment, payment or other health care operations, the disclosure by CMS to a CAP vendor of the patient contact information (address and telephone), date of birth, allergies, height, weight, ICD-9 codes, supplemental health insurance information and Medicaid information is permitted to process and pay the claim.

Administrative burden and dispensing fee

The proposed CAP rule states, "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." 70 Fed. Reg. 10755. This position is mirrored in the interim final rule, "Although we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians." 70 Fed. Reg. 39049. MGMA flatly rejects this assertion. Under the CAP as defined in the interim final rule, medical group practices will be required to keep an inventory of CAP drugs and file duplicative claims data to participate. Providers purchasing drugs through the ASP+6 do not carry these burdens.

MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.8 percent per year over the last 10 years. In fact, between 2001 and 2003, MGMA data show that operating costs increased more than 10.9 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare payments and do not capture new administrative burdens such as the keeping of a drug inventory or the filing of duplicative claims data in drug orders.

In the 2005 final Medicare physician fee schedule, CMS recognized the cost related to the dispensing of drugs. As codified in 42 CFR 414.1001, the agency provides supplying and dispensing fees to pharmacies for oral cancer and inhalation drugs. For oral drugs the supplying fee is $24. 42 CFR 414.1001(a). In 2005, CMS significantly increased the dispensing fees for inhalation drugs, from $5 a month to $57 for a 30-day supply and to an $80 fee for a 90-day supply. 42 CFR 414.1001(c) and (d). Additionally, pharmacies providing drugs to patients during the first month after a transplant are given a $50 supplying fee. 42 CFR 414.1001(b). It is ironic that CMS recognizes the concern and cost of providing drugs to

patients in the context of pharmacies but is unwilling to recognize the cost associated with participation in the CAP program.

MGMA strongly recommends that the PPAC urge CMS to reimburse providers for the cost associated with the additional administrative burdens mandated by CAP participation. Provider costs will vary by the sophistication of practice claims processing and supply/drug inventory systems. Nevertheless, there still remains an element of human interaction with the system since providers need to identify what drugs are received in the mail, which patients the drugs are intended for and the dispensing date.

MGMA data shows that the average cost per physician for preparing and processing a claim is approximately $20. MGMA feels confident that this data is similar to that of costs associated with the proposed CAP order which is more like a claim than a prescription as defined by a majority of state laws. *Therefore, MGMA recommends that PPAC advise CMS to reimburse physicians a dispensing fee of $20 to compensate physicians for the new burden of keeping an inventory log and filing an order which requires intensive information not required in private drug orders reimbursed under the ASP+6 methodology*.

If CMS adopts the changes recommended by MGMA and reduces the requirements of the CAP order, an administrative cost is still associated with keeping an inventory, filing the CAP order and tracking the prescription number. Again, these precise costs are not associated with the ASP+6 system. MGMA estimates that these costs are approximately $5, using administrative costs identified in our cost surveys. *MGMA recommends that, regardless of the nature of the CAP order, PPAC should also suggest that CMS implement a dispensing fee to compensate CAP physicians for the costs associated with participation in the program.*

Prompt claims filing

In the proposed rule, CMS proffers evidence that "75 percent of physician claims are currently filed within 14 days." 70 Fed. Reg. 10755. While MGMA data mirrors the CMS finding for large group practices and facility-based physicians, MGMA data indicates that multi-specialty and small group practices take longer periods to file claims than the average. Therefore, MGMA asserts that a longer timeline must be established to accommodate all practitioners.

The Medicare program currently permits providers to submit claims generally within one year from the date of service. 42 CFR 424.44(a). The interim final rule stipulates that CAP physicians agree to file

claims within 14 days of service. The abrupt modification of claims submission deadline from 365 to 14 days is an incredible change that is not substantiated by the arguments and observations of CMS in the interim final rule. *For these reasons, MGMA recommends that PPAC urge CMS to redefine prompt claims filing for the CAP to be at a minimum 30 business days from the date of service.*

Removing drugs from the Sustainable Growth Rate

MGMA continues to urge PPAC to work with CMS to convince the Agency to remove Part B covered drugs from the calculation used to determine Medicare physician updates beginning with the base year. This administrative action would help to mitigate the impact of the projected cuts and facilitate your efforts to establish long-term improvements to this broken reimbursement system. Such administrative change also represents the right thing to do from a policy perspective.

The definition used by CMS for "physician services" in the sustainable growth rate (SGR) formula inappropriately includes the cost of physician administered outpatient prescription drugs. Medicare's coverage of costly prescription drugs administered in the physician's office has been a significant factor in the growth of Medicare expenditures. Since 1996 (the SGR base year), SGR spending for physician-administered drugs has more than doubled. These expenses reflect patient acquisition of products rather than services rendered by a medical professional and therefore are different than "physician services." Their inclusion in the definition of physician services runs counter to CMS' stated goal of paying appropriately for drugs and physician services.

A separate definition of physician services clearly distinguishes physician administered outpatient prescription drugs from services rendered by physicians. CMS adopted this definition in the December 12, 2002, "Inherent Reasonableness" rule. 67 Fed. Reg. 76684. The definition of physician services must be applied consistently for fair and equitable administration of the Medicare program. Furthermore, the recent rule reforming the payment system for physician-administered prescription drugs refines a separate venue to address the utilization and cost of drugs. MGMA has strongly advocated that CMS remove prescription drug expenditures from the definition of "physician services" used to calculate the physician reimbursement update, beginning with the 1996 base year. Although this would not retroactively impact reimbursements between the base year and 2005, it would appropriately correct the figures on which future updates are based and represent better Medicare policy. *For these reasons, we appeal to the PPAC to recommend to CMS the removal of prescription drug expenditures from the SGR formula as explained above.*

Conclusion

Thank you for the opportunity to share our concerns on the implementation of the CAP. MGMA realizes that you have been called upon to accomplish an extremely difficult and complex task. We applaud your commitment to America's seniors and look forward to working with you and CMS to address the upcoming implementation of this program.